IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants:	Edgardo Costa Maianti et al.	Attorney Docket: DID1047US
Serial No.:	10/805,165	Group Art Unit: 3761
Filed:	March 18, 2004	Examiner: Paula L. Craig
For:	DEVICE AND METHODS FOR PROCESSING BLOOD IN EXTRACORPOREAL CIRCULATION	

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed June 11, 2007 from the Final Rejection of claims 1 to 10 of the above-identified application, as set forth in the Final Office Action mailed February 9, 2007. Please charge our Deposit Account No. 16-2312 in the amount of $620.00 to cover the fee for filing an appeal brief ($500.00) and the fee for a one month extension of time ($120.00). If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 16-2312. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account. Appellants respectfully request reconsideration and reversal of the Examiner's rejection of the pending claims.

Certificate of Electronic Transmission (37 C.F.R. § 1.8)

I hereby certify that this paper is being transmitted to the U.S. Patent and Trademark Office electronic filing system on the date indicated below.

Date: September 11, 2007 **Signature:** Jodi Jung

Name: Jodi Jung

As required by 37 C.F.R. § 41.37, this Brief contains the following items under the headings and in the order suggested therein.

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(1) REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, Sorin Group Italia S.r.l.

(2) RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellants or Appellants' representative that will have a bearing on the Board's decision in the present appeal.

(3) STATUS OF CLAIMS

Claims 1 to 10 were pending in this application at the time this appeal was filed. Appellants are filing contemporaneously with this Brief an Amendment cancelling claims 6 to 10 pursuant to 37 C.F.R. § 41.33(b)(1) in order to simplify the issues on appeal. After entry of the Amendment claims 1 to 5 will be pending in this application. Claims 1 to 5 are rejected and are the subject of this appeal.

(4) STATUS OF AMENDMENTS

On February 9, 2007, the Examiner issued a Final Rejection. On May 9, 2007, Appellants filed an Amendment and Response. In an Advisory Action mailed May 25, 2007, Appellants were notified that the amendments made in the May 9, 2007 Amendment and Response had not been entered. Appellants are

filing contemporaneously with this Brief an Amendment cancelling claims 6 to 10 pursuant to 37 C.F.R. § 41.33(b)(1) in order to simplify the issues on appeal.

(5) SUMMARY OF CLAIMED SUBJECT MATTER

There is one independent claim, claim 1, pending and on appeal. Below Appellants provide a summary of the claimed subject matter in accordance with 37 C.F.R. § 41.37(c)(1)(v) with reference to support found in the specification and drawings.

A. Independent claim 1 and associated dependent claims

1. Claim 1

The invention as recited in claim 1 relates to an integrated device 1 for oxygenating and filtering blood flowing through an extracorporeal blood circuit. The integrated device 1 for oxygenating and filtering blood flowing through an extracorporeal blood circuit comprises: (i) a blood reservoir 2, (ii) a blood pump 4, (iii) a heat exchanger 5, (iv) an oxygenator 6, (v) an arterial blood filter 7, and (vi) a monolithic housing (FIG. 1; pages 5 and 6). The blood reservoir 2 has an inlet 2a for receiving venous blood and an outlet 2f for supplying venous blood (FIG. 1; page 3, lines 11 and 12; page 5, lines 1 to 10). The blood pump 4 has an inlet connected to receive blood from the outlet 2f of the blood reservoir 2 and an outlet 4b (FIG. 1; page 3, lines 12 to 15; page 5, lines 10 to 12). The heat exchanger 5 has a blood inlet 5a connected to receive venous blood from the outlet of the pump 4 and a blood outlet 5b for supplying temperature controlled venous blood, the blood inlet 5a being located below the blood outlet 5b to define a blood flow path from a bottom of the heat exchanger 5 to a top of the heat exchanger 5 (FIG. 1; page 3, lines 12 to 16; page 5, lines 11 to 15). The oxygenator 6 has an inlet 6a connected to receive venous blood from the outlet 5b of the heat exchanger 5 and

an outlet 6b for supplying oxygenated blood (FIG. 1; page 3, lines 15 to 17; page 5, lines 14 to 16). The arterial blood filter 7 has an inlet connected to receive oxygenated blood from the outlet 6b of the oxygenator 6 and an outlet 7a for supplying filtered oxygenated blood (FIG. 1; page 3, lines 16 to 19; page 5, lines 16 to 18). The monolithic housing includes a first portion for defining the blood reservoir 2, a second portion for defining the blood pump 4, a third portion for defining the heat exchanger 5, a fourth portion for defining the oxygenator 6 and a fifth portion for defining the arterial blood filter 7 (page 3, lines 19 to 23).

2. Claim 3

Claim 3 depends from claim 1 through claim 2 and further limits claim 1. Claim 3 requires that the blood pump 4 be a centrifugal pump (page 2, line 15; page 5, lines 10 to 14). Further, the centrifugal pump 4 is positioned within the monolithic housing such that the axis of the centrifugal pump 4 is horizontal (FIG. 1; page 4, lines 10 to 11; page 5, lines 19 to 21).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1, 2, 4, and 5 have been rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,770,149 to Raible in view of U.S. Patent No. 5,039,482 to Panzani et al. (Panzani).

Claim 3 has been rejected under 35 U.S.C. § 103(a) as being obvious over Raible in view of Panzani, and further in view of U.S. Patent No. 5,924,848 to Izraelev.

(7) ARGUMENT

A. Claims 1, 2, 4, and 5 have been rejected under 35 U.S.C. § 103(a) as being obvious over Raible in view of Panzani

This rejection is based upon the combination of Raible and Panzani. Both Raible and Panzani disclose integrated blood oxygenation systems which include an integrated structure housing some of the components of the system. However, the various components are integrated into these integrated structures very differently. In Raible, the integrated system includes a blood pump located at the top of an integrated structure. A heat exchanger is positioned below the blood pump and a membrane oxygenator is positioned below the heat exchanger. (Raible, col. 2, lines 2 to 6). The preferred direction of blood flow through the pump/heat exchanger/membrane oxygenator is top to bottom. (Raible, col. 2, lines 15 to 17). The system may optionally include a blood reservoir, preferably mounted on top of the blood pump. (Raible, col. 3, lines 56 to 59). In Panzani the integrated structure includes a reservoir, an oxygenator below the reservoir and a heat exchanger below the oxygenator. (Panzani, col. 1, lines 40 to 46). Panzani discloses a pump which is not integrated into the integrated structure but which is connected in an external tubing line connected between the outlet of the reservoir and the inlet of the heat exchanger which is located at the bottom of the integrated structure. (Panzani, col. 3, lines 1 to 10; FIG. 1).

With respect to claim 1 in the Final Office Action of February 9, 2007, the Examiner acknowledges that Raible does not teach the blood inlet being located below the blood outlet to define a blood flow path from a bottom of the heat exchanger to a top of the heat exchanger. However, the Examiner cites Panzani as confirming that it is well known in the art to have a blood inlet located below the blood outlet to define a blood flow path from a bottom of the heat exchanger to a

top of the heat exchanger. The Examiner further states that Panzani teaches that this arrangement provides a compact versatile structure and reduces connecting lines to facilitate installation and operation of the device. Therefore, the Examiner concludes that it "would have been obvious to one of ordinary skill in the art at the time of the invention to modify Raible '149 to include a blood inlet located below the blood outlet to define a blood flow path from a bottom of the heat exchanger to a top of the heat exchanger, as taught by Panzani, to provide a compact versatile structure and reduce connecting lines to facilitate installation and operation..."

In the Advisory Action of May 25, 2007, the Examiner states that both top-to-bottom and bottom-to-top arrangements for blood flow are known and that a person of ordinary skill in the art would have expected such rearrangement of parts to be a matter of convenience as either would perform equally well. The Examiner concludes that "Raible indicates that what is important is that the flow of heat exchange fluid should be counterdirectional to the flow of blood (col. 6, lines 11-18)." (Advisory Action, May 25, 2007, page 2, continuation of paragraph 11). Appellants disagree.

A person of skill in the art would have no reason to modify Raible in accordance with Panzani. Appellants especially wish to point out that the Examiner's conclusion that "Raible indicates that what is important is that the flow of heat exchange fluid should be counterdirectional to the flow of blood" only conveys a portion of what Raible teaches. Although Raible teaches the importance of counterdirectional flow Raible also expresses a clear preference for the flow paths of blood and heat exchange fluid. Specifically, Raible states that "[t]he preferred direction of blood flow through the pump/heat exchanger/membrane oxygenator component is top to bottom, while the preferred directions of gas flow and heat-exchange-fluid flow is bottom to top." (Raible, col. 2, lines 15 to 18). Thus, the Examiner's conclusion that it would be obvious to modify Raible to

include a blood inlet located below the blood outlet to define a blood flow path from a bottom of the heat exchanger to a top of the heat exchanger is not only contrary to the express teaching of Raible but also ignores the fact that Raible discloses a system where components are integrated into a single housing which makes it difficult or impossible to modify one component of the system without impacting the function or design of the remainder of the components of the system.

In this situation it is not clear how the modification suggested by the Examiner could be made to the device disclosed in Raible without compromising the goals and objectives the device is meant to achieve. For example, if one were to use the structure as disclosed but reverse the flow path of blood through the heat exchanger such modification would require the addition of either external (or internal) tubing lines between the outlet of the pump mounted above the heat exchanger to the inlet of the heat exchanger located at the bottom of the heat exchanger and from the outlet of the heat exchanger located at the top of the heat exchanger to the inlet of the oxygenator located below the heat exchanger. Such a modification would require a similar rerouting of the flow of heat exchange fluid through the device if the preferred countercurrent flow path of blood and heat exchange fluid were to be maintained. The additional lines would unnecessarily increase the complexity of the device and also increase the priming volume which is undesirable (Raible, col. 1, lines 35 to 44). If, on the other hand, the components of the device disclosed in Raible were rearranged in or to achieve the modification suggested by the Examiner then a significant redesign of the entire product would be required. One way to rearrange the components would be to position the heat exchanger below the oxygenator as disclosed in Panzani with the pump remaining at the top of the integrated structure. That would require not only substantial redesign of the integrated structure including its housing and fluid flow paths but would also require the undesirable addition of an external tubing line or

conduit to connect the outlet of the pump at the top of the structure to the inlet of the heat exchanger at the bottom of the structure. Appellants submit there is no obvious way to mount the centrifugal pump of Raible with its top mounted blood inlet at the bottom of the integrated structure. Further, even if a person of skill in the art was able to position the pump at the bottom of the integrated structure that would require the addition of an undesirable external tubing line or conduit between the outlet of the optional blood reservoir at the top of the integrated structure and the inlet of the pump at the bottom of the integrated structure. For all of these reasons Appellants believe that the Examiner's rejection of these claims was in error. Therefore, Appellants submit that claims 1, 2, 4 and 5 are allowable.

B. Claim 3 has been rejected under 35 U.S.C. § 103(a) as being obvious over Raible in view of Panzani, and further in view of Izraelev

Claim 3 depends from claim 1 through claim 2 and adds the further limitation that the centrifugal pump is positioned such that the axis of the centrifugal pump is horizontal. In the Final Office Action the Examiner states that Raible teaches a centrifugal pump having an axis and the centrifugal pump being positioned within the monolithic housing. The Examiner further states that Izraelev teaches a centrifugal pump for pumping blood in which the axis of the pump may be horizontal or vertical. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to modify Raible or Raible/Panzani to include the axis of the centrifugal pump being vertical or horizontal, as taught by Izraelev. Appellants disagree with the Examiner and believe claim 3 is allowable for at least the reasons stated above and the additional reasons set forth below.

As stated above Raible teaches that the preferred direction of blood flow through the pump/heat exchanger/membrane oxygenator component is top to bottom. Accordingly, Raible positions the centrifugal pump with the axis vertical. Neither Panzani nor Izraelev provide a person of skill in the art with any reason to modify or alter that preferred position. Izraelev discloses a centrifugal pump with a rotor that has a spin axis that can be altered because of a change-of-position of the housing which allows the spin axis to be about the horizontal axis as well as the vertical axis. (Izraelev, col. 3, lines 55 to 59). However, Izraelev discloses the pump in the drawings with the axis in the vertical position and discusses the horizontal position of the axis only in connection with the gyroscopic feature of the rotor which stabilizes the impeller when the axis of the housing is rotated relative to the spin axis of the rotor. (Izraelev, col. 3, lines 52 to 56). Izraelev provides no reason for a person of skill in the art to position the centrifugal pump with its axis horizontal. Therefore, Appellants believe that claim 3 is allowable.

(8) SUMMARY

For the reasons discussed above, claims 1 to 5 are not properly rejected under 35 U.S.C. § 103.

Appellants respectfully submit that the written description fully supports the pending claims and that the art cited does not render the claims obvious and that the claims are patentable over the cited art. Reversal of the rejection and allowance of the pending claims are respectfully requested.

If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 16-2312. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

Date: September 11, 2007

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CLAIMS APPENDIX

1. (Previously presented) An integrated device for oxygenating and filtering blood flowing through an extracorporeal blood circuit comprising:

a blood reservoir having an inlet for receiving venous blood and an outlet for supplying venous blood;

a blood pump having an inlet connected to receive blood from the outlet of the blood reservoir and an outlet;

a heat exchanger having a blood inlet connected to receive venous blood from the outlet of the pump and a blood outlet for supplying temperature controlled venous blood, the blood inlet being located below the blood outlet to define a blood flow path from a bottom of the heat exchanger to a top of the heat exchanger;

an oxygenator having an inlet connected to receive venous blood from the outlet of the heat exchanger and an outlet for supplying oxygenated blood;

an arterial blood filter having an inlet connected to receive oxygenated blood from the outlet of the oxygenator and an outlet for supplying filtered oxygenated blood; and

a monolithic housing including a first portion for defining the blood reservoir, a second portion for defining the blood pump, a third portion for defining the heat exchanger, a fourth portion for defining the oxygenator and a fifth portion for defining the arterial blood filter.

2. (Original) The integrated device of claim 1 wherein the blood pump comprises a centrifugal pump.

3. (Original) The integrated device of claim 2 wherein the centrifugal pump has an axis and wherein the centrifugal pump is positioned within the monolithic housing such that the axis of the centrifugal pump is horizontal.

4. (Original) The integrated device of claim 1 wherein the blood reservoir comprises a venous reservoir and a cardiotomy reservoir.

5. (Original) The integrated device of claim 4 wherein the monolithic housing comprises connection means for allowing removable connection of the first portion.

Claims 6 to 10 (Canceled).

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.